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Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE SELENIOUS ACID LITIGATION	Civil Action No. 2:24-cv-7791-BRM-CLW (CONSOLIDATED)

SUN'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS TO THE COMPLAINT

Defendants Sun Pharmaceutical Industries Limited ("SPIL") and Sun Pharmaceutical Industries, Inc. ("SPINC") (collectively, "Sun" or "Defendants"), by and through their undersigned attorneys, provide the following answers, separate defenses, and counterclaims to the Complaint ("Complaint") (D.I. 1) of Plaintiff American Regent ("ARI" or "Plaintiff"). This pleading is based upon Sun's knowledge as to its own activities and upon information and belief as to other matters. Pursuant to Fed. R. Civ. P. 8(b)(3), Sun denies all allegations in Plaintiff's Complaint except those specifically admitted below:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, arising from Sun's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application No. 219547 ("the ANDA") which contains a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certification") seeking approval to engage in the commercial manufacture, use, sale, and/or importation of a generic version of ARI's Selenious Acid products ("the ANDA Product") prior to the expiration of United States Patent No. 12,150,957 ("the '957 patent" or the "Asserted Patent"). As discussed below, this case involves the same ANDA No. 219547 and thus is a related case to *American Regent, Inc. v. Sun Pharmaceutical Industries Limited, et al,* C.A. No. 24-7810 (D.N.J.) (the "Related Action").

ANSWER: Sun admits that this case involves the same ANDA No. 219547 ("Sun's ANDA") and is a related case to *American Regent, Inc. v. Sun Pharmaceutical Industries Limited, et al,* C.A. No. 24-7810 (D.N.J.). The remaining allegations in paragraph 1 comprise conclusions of law to which no answer is required. To the extent a response is required, Sun admits Plaintiff purports to bring an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq*. Sun admits to filing an amendment to Sun's ANDA with the FDA seeking approval of the product described therein ("Sun's Proposed ANDA Product") prior to the expiration of United States Patent No. 12,150,957 ("the '957 patent") with a Paragraph IV certification. Sun denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

THE PARTIES

2. ARI is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

ANSWER: Sun is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in this paragraph of the Complaint and therefore denies the same.

3. On information and belief, Sun Pharmaceutical Industries Limited is a corporation organized and existing under the laws of India with its principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400063, India.

ANSWER: Sun admits that Sun Pharmaceutical Industries Limited is a company organized and existing under the laws of India with a place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai 400063, India. Sun denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

4. On information and belief, Sun Pharmaceutical Industries, Inc. is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 2 Independence Way, Princeton, New Jersey 08450.

ANSWER: Sun admits that Sun Pharmaceutical Industries, Inc. is organized under the laws of Delaware with a place of business located at 2 Independence Way, Princeton, New Jersey 08540. Sun denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

JURISDICTION AND VENUE

5. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: The allegations in paragraph 5 comprise conclusions of law to which no answer is required. To the extent a response is required, Sun admits that Plaintiff purports to bring a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.* Sun does not contest jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a) for this matter only. Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

6. On information and belief, this Court has personal jurisdiction over Sun Pharmaceutical Industries Limited, under the New Jersey state long arm statute and consistent with due process of law because Sun has extensive contacts with the State of New Jersey and regularly does business in this judicial district. Further, Sun plans to sell its ANDA Product in the State of New Jersey, which provides an independent basis for personal jurisdiction here.

ANSWER: The allegations in paragraph 6 comprise conclusions of law to which no answer is required. To the extent a response is required, solely for the purposes of Plaintiff's claims against Sun in this case as they apply to Sun's Proposed ANDA Product described in Sun's ANDA No. 219547, SPIL does not contest personal jurisdiction, and expressly reserves the right to contest personal jurisdiction in any other case as to any other part. Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

7. On information and belief, this Court has personal jurisdiction over Sun Pharmaceutical Industries, Inc., under the New Jersey state long arm statute and consistent with due process of law, because Sun Pharmaceutical Industries, Inc. maintains its principal place of business in New Jersey.

ANSWER: The allegations in paragraph 7 comprise conclusions of law to which no answer is required. To the extent a response is required, solely for the purposes of Plaintiff's claims against Sun in this case as they apply to Sun's Proposed ANDA Product described in Sun's ANDA No. 219547, SPINC does not contest personal jurisdiction, and expressly reserves the right to contest personal jurisdiction in any other case as to any other part. Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

8. This Court has personal jurisdiction over Sun Pharmaceutical Industries Limited because it has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contact with the State of New Jersey. On information and belief, Sun Pharmaceutical Industries Limited regularly and continuously transacts business within New Jersey, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey. On information and belief, Sun Pharmaceutical Industries Limited derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

ANSWER: The allegations in paragraph 8 comprise conclusions of law to which no answer is required. To the extent a response is required, solely for the purposes of Plaintiff's claims against Sun in this case as they apply to Sun's Proposed ANDA Product described in Sun's ANDA No. 219547, SPIL does not contest personal jurisdiction, and expressly reserves the right to contest

personal jurisdiction in any other case as to any other part. Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

9. This Court has personal jurisdiction over Sun Pharmaceutical Industries, Inc. by virtue of, inter alia, its systematic and continuous contacts with the State of New Jersey. On information and belief, Sun Pharmaceutical Industries, Inc.'s principal place of business is in Princeton, New Jersey. On information and belief, Sun Pharmaceutical Industries, Inc. purposefully has conducted and continues to conduct business in this judicial district. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Sun Pharmaceutical Industries, Inc.

ANSWER: The allegations in paragraph 9 comprise conclusions of law to which no answer is required. To the extent a response is required, Sun admits that SPINC has a place of business in Princeton, New Jersey. Solely for the purposes of Plaintiff's claims against Sun in this case as they apply to Sun's Proposed ANDA Product described in Sun's ANDA No. 219547, SPINC does not contest personal jurisdiction, and expressly reserves the right to contest personal jurisdiction in any other case as to any other part. Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

10. On information and belief, Sun Pharmaceutical Industries, Inc. and Sun Pharmaceutical Industries Limited work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

ANSWER: The allegations in paragraph 10 comprise conclusions of law to which no answer is required. To the extent a response is required, Sun denies the allegations in Paragraph 10.

11. On information and belief, Sun Pharmaceutical Industries, Inc. is the United States agent acting at the direction of, and for the benefit of, Sun Pharmaceutical Industries Limited regarding the ANDA.

ANSWER: The allegations in paragraph 11 comprise conclusions of law to which no answer is required. To the extent a response is required, Sun admits that SPINC is the U.S. Agent

for ANDA No. 219547. Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

12. This Court has personal jurisdiction over Sun because Sun has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contact with the State of New Jersey. On information and belief, Sun Pharmaceutical Industries, Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Id. No. 0101055400, and Sun Pharmaceutical Industries, Inc. is also licensed to do business with the New Jersey Department of Health as a "Manufacturer and Wholesale[r]" of pharmaceuticals in the State of New Jersey under Registration Number 5003358. On information and belief, Sun regularly and continuously transacts business within New Jersey, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey. On information and belief, Sun derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

ANSWER: The allegations in paragraph 12 comprise conclusions of law to which no answer is required. To the extent a response is required, Sun does not contest personal jurisdiction in this Court for the purposes of this action only. Sun admits that it has a place of business in New Jersey. Sun denies any remaining allegations in paragraph 12. Allegations not expressly admitted are denied.

13. This Court has personal jurisdiction over Sun because, on information and belief, Sun derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this judicial district.

ANSWER: The allegations in paragraph 13 comprise conclusions of law to which no answer is required. To the extent a response is required, solely for the purposes of Plaintiff's claims against Sun in this case as they apply to Sun's Proposed ANDA Product described in Sun's ANDA No. 219547, Sun does not contest personal jurisdiction, and expressly reserves the right to contest personal jurisdiction in any other case as to any other part. Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

14. This Court has personal jurisdiction over Sun Pharmaceutical Industries Limited because it has previously availed itself of the legal protections of the State of New Jersey by,

among other things, not contesting personal jurisdiction and through the assertion of counterclaims in suits brought in New Jersey, including in at least *Dexcel Pharma Technologies Ltd. et al. v. Sun Pharma Global FZE et al.*, No. 15-08017, ECF No. 18 (D.N.J. Feb. 5, 2016).

ANSWER: The allegations in paragraph 14 comprise conclusions of law to which no answer is required. To the extent a response is required, Sun admits that SPIL has previously not contested personal jurisdiction in certain cases and has filed counterclaims in the District of New Jersey. Solely for the purposes of Plaintiff's claims against Sun in this case as they apply to Sun's Proposed ANDA Product described in Sun's ANDA No. 219547, Sun does not contest personal jurisdiction, and expressly reserves the right to contest personal jurisdiction in any other case as to any other part. Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

15. This Court has personal jurisdiction over Sun Pharmaceutical Industries, Inc. because it has previously availed itself of the legal protections of the State of New Jersey by, among other things, not contesting personal jurisdiction and through the assertion of counterclaims in suits brought in New Jersey, including in at least *Astellas Pharma Inc. v. Sun Pharm. Industries, Inc*., C.A. No. 22-7357 (D.N.J.) and *Orexo AB v. Sun Pharm. Industries Ltd.*, C.A. No. 21-17941 (D.N.J.).

ANSWER: The allegations in paragraph 15 comprise conclusions of law to which no answer is required. To the extent a response is required, Sun admits that SPINC has previously not contested personal jurisdiction in certain cases and has filed counterclaims in the District of New Jersey. Solely for the purposes of Plaintiff's claims against Sun in this case as they apply to Sun's Proposed ANDA Product described in Sun's ANDA No. 219547, Sun does not contest personal jurisdiction, and expressly reserves the right to contest personal jurisdiction in any other case as to any other part. Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

16. This Court has personal jurisdiction over Sun because, *inter alia*, Sun has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will

lead to foreseeable harm and injury to ARI in New Jersey. Further, on information and belief, following approval of the ANDA, Sun will make, use, import, sell, and/or offer for sale the ANDA Products in the United States, including in New Jersey, prior to the expiration of the Asserted Patent.

ANSWER: The allegations in paragraph 16 comprise speculation of future events and conclusions of law to which no answer is required. To the extent a response is required, solely for the purposes of Plaintiff's claims against Sun in this case as they apply to Sun's Proposed ANDA Product described in Sun's ANDA No. 219547, Sun does not contest personal jurisdiction, and expressly reserves the right to contest personal jurisdiction in any other case as to any other part. Sun denies all remaining allegations in this paragraph of the Complaint and specifically denies that "Sun has committed an act of patent infringement under 35 U.S.C. § 271(e)(2)," that it "intends a future course of conduct that includes acts of patent infringement in New Jersey," and that its "acts have led and will lead to foreseeable harm and injury to ARI in New Jersey." Allegations not expressly admitted are denied.

17. In the alternative, this Court has personal jurisdiction over Sun Pharmaceutical Industries Limited because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) ARI's claims arise under federal law; (b) Sun Pharmaceutical Industries Limited is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Sun Pharmaceutical Industries Limited has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Sun Pharmaceutical Industries Limited satisfies due process.

ANSWER: The allegations in paragraph 17 comprise conclusions of law to which no answer is required. To the extent a response is required, solely for the purposes of Plaintiff's claims against Sun in this case as they apply to Sun's Proposed ANDA Product described in Sun's ANDA No. 219547, Sun does not contest personal jurisdiction, and expressly reserves the right to contest personal jurisdiction in any other case as to any other part. Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

18. Venue is further proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

ANSWER: The allegations in paragraph 18 comprise conclusions of law to which no answer is required. To the extent a response is required, solely for the purposes of Plaintiff's claims against Sun in this case as they apply to Sun's Proposed ANDA Product described in Sun's ANDA No. 219547, Sun does not contest venue, and expressly reserves the right to contest venue in any other case as to any other part. Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

19. On information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) at least because Sun Pharmaceutical Industries, Inc. has committed acts of infringement in New Jersey and has a regular and established place of business in New Jersey. Sun Pharmaceutical Industries Limited is a foreign company not residing in any United States judicial district and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

ANSWER: The allegations in paragraph 19 comprise conclusions of law to which no answer is required. To the extent a response is required, solely for the purposes of Plaintiff's claims against Sun in this case as they apply to Sun's Proposed ANDA Product described in Sun's ANDA No. 219547, Sun does not contest venue, and expressly reserves the right to contest venue in any other case as to any other part. Sun denies all remaining allegations in this paragraph of the Complaint and specifically that SPINC "has committed acts of infringement in New Jersey." Allegations not expressly admitted are denied.

20. On information and belief, Sun has committed acts of infringement under the meaning of 28 U.S.C. § 1400(b) by submitting the ANDA to the FDA, by taking steps indicating its intent to market the ANDA Products in New Jersey, and by the acts that it non-speculatively intends to take in New Jersey if the ANDA receives final FDA approval.

ANSWER: The allegations in paragraph 20 comprise conclusions of law to which no answer is required. To the extent a response is required, Sun admits that Sun has submitted ANDA No. 219547 to the FDA. Sun denies all remaining allegations in this paragraph of the Complaint.

21. On information and belief, Sun Pharmaceutical Industries, Inc. has a regular and established place of business in New Jersey under the meaning of 28 U.S.C. § 1400(b) because, *inter alia*, its principal place of business is in New Jersey. As set forth above, on information and belief, Sun Pharmaceutical Industries, Inc. maintains regular and established places of business in New Jersey, including its headquarters, offices, laboratories, and/or facilities at 2 Independence Way, Princeton, New Jersey 08450.

ANSWER: The allegations in paragraph 21 comprise conclusions of law to which no answer is required. To the extent a response is required, Sun admits that SPINC has a place of business at 2 Independence Way, Princeton, New Jersey 08540. Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

22. On information and belief, Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc. have taken steps in New Jersey, including preparing the ANDA and communicating with the FDA regarding the ANDA, that indicate their intent to market the ANDA Products. As set forth above, on information and belief, if the ANDA is approved, Sun intends to commit acts of patent infringement in New Jersey, including marketing, distributing, offering for sale, and/or selling the ANDA Products.

ANSWER: Sun admits that SPIL, through its U.S. Agent SPINC, filed ANDA No. 219547. Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

BACKGROUND

23. ARI holds New Drug Application ("NDA") No. 209379 for Selenious Acid ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL), (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL), and (3) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)), which was originally approved by the FDA on April 30, 2019, which ARI manufactures and sells in this judicial district and throughout the United States.

ANSWER: Sun admits that ARI is identified as the Applicant Holder of NDA No. 209379 according to Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book." Sun further admits that the Orange Book lists April 30, 2019 as the approval date for NDA No. 209379 for Selenious Acid (eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL)). Sun lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph, and therefore denies the same.

24. The use of ARI's Selenious Acid products is covered by one or more claims of the Asserted Patent.

ANSWER: The allegations in paragraph 24 comprise conclusions of law to which no answer is required. To the extent a response is required, Sun lacks information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of this paragraph, and therefore denies the same.

25. ARI is the owner of the '957 patent, entitled "Trace element compositions, methods of making and use," which was duly and legally issued on November 26, 2024. A copy of the '957 patent is attached as Exhibit A.

ANSWER: Sun admits that Plaintiff purports to attach a copy of the '957 patent to the Complaint as Exhibit A. Sun admits that the '957 patent states on its face that it was issued on November 26, 2024 and is titled "Trace element compositions, methods of making and use." Sun lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph, and therefore denies the same.

26. The '957 patent has been listed in connection with ARI's Selenious Acid products in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book").

ANSWER: Sun admits that the '957 patent is listed in connection with NDA No. 209379 in the Orange Book. Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

27. As indicated in the Orange Book, the patent expiration date for the '957 patent is July 1, 2041.

ANSWER: Sun admits that the Orange Book indicates that the patent expiration date for the '957 patent is July 1, 2041. Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

28. On information and belief, Sun was responsible for preparing the ANDA which contained a Paragraph IV Certification.

ANSWER: Sun admits that SPIL, through its U.S. Agent SPINC, filed ANDA No. 219547. Sun admits that ANDA No. 219547 includes a Paragraph IV certification. Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

29. By letter dated June 11, 2024 ("the Notice Letter"), Sun notified ARI that, pursuant to the Federal Food, Drug, and Cosmetic Act, Sun had submitted the ANDA with a Paragraph IV Certification to the FDA to seek approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product prior to the expiration of U.S. Patent No. 11,998,565 ("the '565 patent"), which is at issue in the Related Action.

ANSWER: Sun admits that, on June 11, 2024, SPIL sent a letter ("Notice Letter") to Plaintiff. Sun admits that, according to the Notice Letter, SPIL seeks approval to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's Proposed ANDA Product prior to the expiration of the '565 patent pursuant to the patent laws. Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

30. On information and belief, Sun submitted the ANDA to the FDA, which contained a Paragraph IV Certification asserting that the '565 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of the ANDA Product, or alternatively, that the '565 patent is invalid.

ANSWER: Sun admits that Sun filed ANDA No. 219547. Sun admits that ANDA No. 219547 includes a Paragraph IV certification, alleging that the '565 patent is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of Sun's Proposed ANDA Product. Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

31. Since ARI received the Notice Letter and filed its complaint against Sun in the Related Action, the '957 patent has been listed in connection with ARI's Selenious Acid products in the Orange Book.

ANSWER: Sun admits that Plaintiff caused the '957 patent to be listed in connection with NDA No. 209379 in the Orange Book. Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

32. On information and belief, the ANDA Product is a generic version of ARI's Selenious Acid products ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL) as its reference listed drug, containing the same or equivalent ingredients in the same or equivalent amounts.

ANSWER: Sun admits that Sun's ANDA No. 219547 identifies Selenious Acid Injection, 600 mcg selenium/10 mL (eq. 60 mcg selenium/mL) from NDA No. 209379 as the reference listed drug. Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

33. In the Notice Letter, Sun disclosed that the ANDA Product is: Selenious Acid Injection, USP, 600 mcg/10 mL (60 mcg/mL) of selenium in a 10 mL pharmacy bulk package.

ANSWER: Sun admits that according to the Notice Letter, Sun's product is selenious acid injection USP, 600 mcg/10 mL (60 mcg/mL) of selenium in a 10 mL pharmacy bulk package. Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

34. On information and belief, the ANDA Product contains the same or equivalent ingredients in the same or equivalent amounts as ARI's Selenious Acid products ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL)).

ANSWER: Sun admits that Sun's Proposed ANDA Product contains 600 mcg selenium/10 mL (60 mcg selenium/mL). Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

35. On information and belief, the ANDA Product will feature the same or equivalent chemical and therapeutic properties as ARI's Selenious Acid products.

ANSWER: Sun admits that ANDA No. 219547 contains information demonstrating the bioequivalence of Sun's Proposed ANDA Product to the reference listed drug from NDA No.

209379. Sun lacks sufficient information to form a belief as to the truth of the allegations that relate to future events, and therefore deny them. Sun denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

COUNT I: INFRINGEMENT OF THE '957 PATENT

36. ARI realleges paragraphs 1–35 as if fully set forth herein.

ANSWER: Sun realleges its answers to the allegations of paragraphs 1-35 as if fully set forth herein.

37. Sun's submission of the ANDA with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product in or into the United States, prior to the expiration of the '957 patent, constitutes direct and indirect infringement of the '957 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

38. On information and belief, the ANDA Product, if approved by the FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Sun or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '957 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Product will occur with Sun's specific intent and encouragement, and will constitute conduct that Sun knows or should know will occur. On information and belief, Sun will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '957 patent.

ANSWER: Denied.

39. On information and belief, Sun's manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, once the ANDA with a Paragraph IV Certification is approved by the FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and/or contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '957 patent, either literally or under the doctrine of equivalents. On information and belief, Sun intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Sun knows that the ANDA Product is especially made or adapted for use in infringing the '957 patent, and that the ANDA Product is not suitable for substantial non-infringing use.

ANSWER: Denied.

40. ARI will be irreparably harmed if Sun is permitted to make, use, sell, offer to sell, and/or import the ANDA Product in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '957 patent, or any later expiration of exclusivity for the '957 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

ANSWER: Denied.

41. Sun has had knowledge of the '957 patent since at least October 11, 2024, when ARI emailed all defendants in the Related Action to inform them that the '957 patent would issue in due course.

ANSWER: Sun admits that ARI sent an email on October 11, 2024 attaching a notice of allowance of U.S. application number 18/672,876 and stated that ARI intends to list this new patent in FDA's Orange Book for its Selenious Acid products shortly after issuance. Sun denies all remaining allegations in this paragraph of the Complaint.

42. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

PRAYER FOR RELIEF

Sun denies that Plaintiff is entitled to judgment or any of the relief sought against Sun in paragraphs (a)-(h) under the heading "PRAYER FOR RELIEF" in the Complaint. Sun demands judgment in its favor.

SEPARATE DEFENSES OF DEFENDANTS

Without prejudice to the denials set forth in its Answer, Sun pleads the following separate defenses in response to Plaintiff's allegations. Sun reserves the right to allege any and all defenses not presently known or revealed during discovery or other analysis.

First Separate Defense

Count I is barred for failure to state a claim upon which relief can be granted.

Second Separate Defense

The claims of the '957 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including but not limited to, §§ 101, 102, 103 and/or 112, and/or based on other judicially created bases for invalidation.

Third Separate Defense

Sun has not infringed, are not infringing, and will not infringe, literally or under the doctrine of equivalents, either directly or by contribution or inducement, any valid and enforceable claim of the '957 patent.

Fourth Separate Defense

Plaintiff may not seek injunctive relief against Sun for at least the reason that Plaintiff's alleged damages are not immediate or irreparable and Plaintiff therefore has an adequate remedy at law.

Fifth Separate Defense

Plaintiff has failed to allege any facts supporting this is an exceptional case or an award of attorneys' fees under 35 U.S.C. § 285 or otherwise. Plaintiff is not entitled to a finding that this case is exceptional under 35 U.S.C. § 285 or otherwise.

Sixth Separate Defense

Plaintiff lacks subject matter jurisdiction for any infringement claim under 35 U.S.C. § 271 (a), (b), and (c).

Additional Defenses

Sun reserves the right to allege additional separate defenses as they become known through the course of discovery.

COUNTERCLAIMS

Without admitting any of the allegations of Plaintiff/Counterclaim-Defendant American Regent, Inc. ("Plaintiff/Counterclaim-Defendant" or "ARI") other than those expressly admitted herein, and without prejudice to Defendants/Counterclaim-Plaintiffs Sun Pharmaceutical Industries Limited ("SPIL") and Sun Pharmaceutical Industries, Inc. ("SPINC") (collectively, "Sun") to plead additional counterclaims as the facts of the matter warrant, Sun asserts the following counterclaims against ARI:

NATURE OF THE ACTION

1. These Counterclaims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and seek a declaratory judgment that Sun's proposed products in Abbreviated New Drug Application ("ANDA") No. 219547 do not and will not infringe any valid and enforceable claim of U.S. Patent No. 12,150,957 ("the '957 patent" or "the patent-in-suit"), and that each and every claim of the '957 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103 and/or 112, and/or based on other judicially created bases for invalidation.

2. Upon information and belief, a true and complete copy of the '957 patent is attached to the Complaint (D.I. 1) as Exhibit A.

PARTIES

3. Defendant/Counterclaim-Plaintiff SPIL is a company incorporated under the laws of India, having a principal place of business in Mumbai, India.

4. Defendant/Counterclaim-Plaintiff SPINC is a company incorporated under the laws of the state of Delaware, having places of business in Princeton, New Jersey and Cranbury, New Jersey.

5. On information and belief, and based on Plaintiff/Counterclaim-Defendant's allegations, Plaintiff/Counterclaim-Defendant ARI is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

6. ARI purports to be the lawful owner of the '957 patent.

7. ARI purports to hold the New Drug Application ("NDA") No. 209379 for Selenious Acid ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL), (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL), and (3) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)) and purports to market, distribute, and sell the selenious acid products.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202 based on an actual controversy among the parties, arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq*.

9. This Court has personal jurisdiction over Plaintiff/Counterclaim-Defendant based on, *inter alia*, its filing of this lawsuit in this jurisdiction, and/or Plaintiff/Counterclaim-Defendant's substantial business in and regular systematic contact with this District. Counterclaim-defendant has also availed itself of this forum in other pending actions, *e.g.*, *American Regent, Inc. v. Gland Pharma Limited*, Civil Action No. 2-24-cv-07756; *American Regent, Inc. v. Zydus Pharmaceuticals (USA) Inc.*, Civil Action No. 2-24-cv-07812.

10. Venue is proper in this judicial district based on 28 U.S.C. §§ 1391 and 1400 and 21 U.S.C. § 355(j)(5)(C)(i)(II).

BACKGROUND

11. According to the United States Food & Drug Administration ("FDA") publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book"), ARI holds an approved New Drug Application ("NDA") No. 209379 for selenious acid solutions.

12. Under 21 U.S.C. § 355(b)(1), an NDA holder must provide to FDA the patent numbers and expiration dates of any patent(s) that the NDA holder believes "claims the drug for which the applicant submitted the [NDA]" or which "claims a method of using such drug." FDA ministerially publishes these patents in the Orange Book.

13. Upon information and belief, and as stated in the Complaint in this matter, ARI is the owner of the '957 patent. Upon information and belief, and as stated on the face of the '957 patent, ARI is the assignee of the '957 patent.

14. Upon information and belief, ARI, itself or through its agents, caused the '957 patent to be listed in the Orange Book as a patent that claims its selenious acid products or a method of using its selenious acid products subject to NDA No. 209379.

15. The '957 patent, on its face, is titled "Trace element compositions, methods of making and use" and has an issue date of November 26, 2024.

16. SPIL submitted ANDA No. 219547 to FDA seeking approval to engage in commercial manufacture, or sale of the products described therein ("Sun's Proposed ANDA Product") in the United States. SPINC is the U.S. Agent for SPIL for ANDA No. 219547.

17. ANDA No. 219547 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '957 patent is invalid, unenforceable, and/or will not be infringed by

the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sun's Proposed ANDA Product.

18. On or around December 18, 2024, SPIL sent a notice letter providing notice of its submission of an amendment to ANDA No. 219547 to FDA ("the Notice Letter") to ARI. The Notice Letter contains notification of SPIL's Paragraph IV Certification to FDA that the '957 patent is invalid, unenforceable, and/or not infringed by Sun's Proposed ANDA Product and the factual and legal bases in support thereof. The Notice Letter also contained an offer of confidential access to ANDA No. 219547 in accordance with 21 U.S.C. § 355(j)(5)(C).

19. On or around December 13, 2024, Plaintiff/Counterclaim-Defendant filed a lawsuit, alleging, *inter alia*, infringement of the '957 patent based on SPIL's filing of ANDA No. 219547.

20. Sun denies it infringes any valid claim of the '957 patent.

21. Absent a ruling from this Court finding the '957 patent is invalid, unenforceable, and/or not infringed by Sun or the products described in ANDA No. 219547, ARI will continue to assert the '957 patent against Sun, hindering the ability of Sun to obtain regulatory approval and to market in the United States the products described in ANDA No. 219547, causing irreparable harm to Sun's businesses and denying Sun patent certainty.

22. ARI has requested both injunctive relief and damages against Sun. Sun has invested significant financial and other resources into the development of Sun's Proposed ANDA Product and in seeking FDA approval. ARI's threats against Sun will continue as long as the disputes identified with respect to the infringement and validity of the '957 patent remain.

23. Accordingly, there is an actual, substantial, and continuing justiciable case and controversy between ARI and Sun regarding the '957 patent, over which this Court can and should exercise jurisdiction and declare the rights of the parties.

COUNT I
(Declaration of Invalidity of the '957 Patent)

24. Sun incorporates by reference Paragraphs 1 through 23 as if fully set forth herein.

25. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Sun and ARI concerning the invalidity of the '957 patent.

26. One or more of the claims of the '957 patent is invalid for failure to comply with one or more of the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

27. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 *et seq.*, Sun is entitled to a declaratory judgment that one or more claims of the '957 patent is/are invalid.

COUNT II
(Declaration of Non-Infringement of the '957 Patent)

28. Sun incorporates by reference Paragraphs 1 through 27 as if fully set forth herein.

29. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Sun and ARI concerning the non-infringement of the '957 patent.

30. Neither the submission of Sun's ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Sun's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '957 patent, either literally or under the doctrine of equivalents, at least because the claims of the '957 patent are invalid, and an invalid claim cannot be infringed.

31. Additionally, for at least the reasons set forth in the Notice Letter of December 18, 2024, neither the submission of Sun's ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Sun's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '957 patent, either literally or under the doctrine of equivalents, at least because Sun's Proposed ANDA Product is not covered by any valid or enforceable claims of the '957 patent.

32. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Sun is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '957 patent, either literally or under the doctrine of equivalents.

EXCEPTIONAL CASE

This case is an exceptional one, and Sun is entitled to an award of its reasonable attorney fees, expenses, and costs under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Sun respectfully requests the Court enter judgment in its favor, granting the following relief:

A. Dismissing the Complaint, with prejudice, and deny Plaintiff the reliefs requested in the Complaint and any relief whatsoever;

B. Deny Plaintiff any award of damages, costs, or fees;

C. Declaration that Sun has not and will not infringe any valid and enforceable claim of the '957 patent;

D. Declaration that all claims of the '957 patent are invalid;

E. Declaration that all claims of the '957 patent are not infringed and will not be infringed by the submission of Sun's ANDA or the manufacture, use, sale, offer for sale, marketing, or importation into the United States of Sun's Proposed ANDA Product;

F. Declaration that this is an exceptional case in favor of Sun under 35 U.S.C. § 285;

G. Declaration that Sun is the prevailing party and awarding its fees, costs, and expenses in this action pursuant to 35 U.S.C. § 285, or any other applicable statute or law;

H. An award to Sun of its costs and expenses in this action pursuant to 28 U.S.C. § 1920, or any other applicable statute; and

I. An award to Sun of such other and further relief as the Court deems just and proper.

Dated: January 8, 2025

Respectfully submitted,

s/ Gregory D. Miller
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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: January 8, 2025

s/Gregory D. Miller
Gregory D. Miller

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, *inter alia*, injunctive and declaratory relief in their respective pleadings.

I hereby certify under penalty of perjury that the foregoing is true and correct.

Dated: January 8, 2025

s/Gregory D. Miller
Gregory D. Miller

CERTIFICATE OF SERVICE

I hereby certify that, on January 8, 2025, the foregoing document described as **DEFENDANTS' ANSWER TO COMPLAINT, SEPARATE DEFENSES AND COUNTERCLAIMS** was served on all counsel of record indicated below via electronic mail.

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Dated: January 8, 2025

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